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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/775,780 | 02/10/2004 | Keren I. Hulkower | 06244.00002 | 9361 |
| 26259 | 7590 | 04/28/2005 | EXAMINER | |
| LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053 | | | VENCİ, DAVID J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1641 | |

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/775,780 | Applicant(s) HULKOWER ET AL. | |
| | Examiner David J. Venci | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 23, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 137-153 is/are pending in the application.
- 4a) Of the above claim(s) 143-147 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 137-142 and 148-153 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 137-153 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on February 10, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/14/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicant's preliminary amendment filed November 23, 2004, which cancelled claims 1-136, and added new claims 137-153. Restriction of new claims 137-153 to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 137-142 and 148-153, drawn to devices and kits, classified in class 435/975, for example.
- II. Claims 143-147, drawn to a method of detection, classified in class 436/55, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products can be used in materially different processes, such as photodynamic processes.

Because these inventions are distinct for the reasons given above and the search required for each group is not required for the other groups, restriction for examination purposes as indicated is proper.

Examiner acknowledges Applicant's election of the invention recited in new claims 137-141, with traverse, in the reply filed on November 23, 2004. The traversal is on the grounds that "the salient input (i.e., analyte and analyte-specific compound) and output features (i.e., detectable compound which can be

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bound by a porphyrin dye to produce a detectable response) are based on the same concept" (see Applicants' Remarks, sentence bridging pp. 9-10). In addition, Applicants argue that "a search of the relevant prior art pertaining to devices comprising an analyte-specific compound that binds to a selected analyte so that a detectable compound is produced; and at least one porphyrin dye which binds the detectable compound thereby producing a detectable response would reveal art related to methods for using the same to detect an analyte" (see Applicants' Remarks, p. 10, second full paragraph). Applicants' arguments have been carefully considered but are not persuasive because a search of the prior art pertaining to Applicants' claimed devices and kits does not necessarily reveal art related to Applicants' claimed methods. For example, a search for Applicants' claimed devices and kits requires a search of prior art related to photodynamic therapy, which does not appear to be related to Applicants' claimed methods. Likewise, a search for Applicants' claimed methods requires a search of prior art related to prosthetic-group-label immunoassay techniques, which does not appear to be related to Applicants' claimed devices and kits. The requirement is considered proper and is made FINAL.

Claims 143-147 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Currently, claims 137-142 and 148-153 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 137-142 and 148-153 are rejected under 35 U.S.C. 102(b) as being anticipated by Humphries et al. (US 4,849,330).

Humphries et al. describe a device comprising an analyte-specific compound (see col. 8, line 47, "antibodies"), an analyte (see col. 8, lines 49-50, "ligands"), a detectable compound (see col. 9, line 41, "redox material"), a porphyrin dye (see col. 7, lines 53-54, "cytochrome C, and cytochrome b₂"), an enzyme conjugated to the analyte-specific compound (see col. 10, lines 56-57, "enzyme conjugated to... reciprocal binding pair member"), a substrate of the enzyme (see col. 10, line 51, "substrates"), a conjugate comprising an enzyme and a non-analyte-specific compound (see col. 9, lines 26-29, "label conjugated to... analyte analog"), a capture analyte-specific compound (see col. 11, line 12, "sandwich immunoassay"), a tracer comprising an analyte molecule bound to an enzyme (see col. 9, lines 26-29, "label conjugated to... analyte"), a receptor molecule (see col. 8, line 47, "antibodies"), and a sample (see col. 9, line 28, "sample").

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 137-142 and 148-153 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 40 of U.S. Patent No. 6,495,102 in view of Humphries et al. (US 4,849,330).

U.S. Patent No. 6,495,102 claims a device (see e.g. claim 1, "nose") comprising at least one porphyrin dye (see e.g. claim 1, "porphyrin"). U.S. Patent No. 6,495,102 does not claim an analyte-specific compound, an analyte, a detectable compound, an enzyme conjugated to the analyte-specific compound, a substrate of the enzyme, a conjugate comprising an enzyme and a non-analyte-specific compound, a capture analyte-specific compound, a tracer comprising an analyte molecule bound to an enzyme, a receptor molecule, and a sample.

However, Humphries et al. describe a device comprising an analyte-specific compound (see col. 8, line 47, "antibodies"), an analyte (see col. 8, lines 49-50, "ligands"), a detectable compound (see col. 9, line 41, "redox material"), an enzyme conjugated to the analyte-specific compound (see col. 10, lines 56-57, "enzyme conjugated to... reciprocal binding pair member"), a substrate of the enzyme (see col. 10, line 51, "substrates"), a conjugate comprising an enzyme and a non-analyte-specific compound (see col. 9, lines 26-29, "label conjugated to... analyte analog"), a capture analyte-specific compound (see col. 11, line 12, "sandwich immunoassay"), a tracer comprising an analyte molecule bound to an enzyme (see col. 9, lines 26-29, "label conjugated to... analyte"), a receptor molecule (see col. 8, line 47, "antibodies"), and a sample (see col. 9, line 28, "sample").

Therefore, it would have been obvious for a person of ordinary skill in the art to modify the nose, as recited in claims 1 and 40 of U.S. Patent No. 6,495,102, by inserting various immunoassay components up it because Humphries et al. discovered a device providing "specific interactions" (see col. 4, line 64) for detecting the presence of "specific components" (see col. 8, lines 33-34) in complex mixtures, such as urine (see col. 8, lines 40-42).

Claims 137-142 and 148-153 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 26 of copending Application No. 10/278421 in view of Humphries et al. (US 4,849,330), or alternatively, claims 1 and 21 of copending Application No. 10/279788 in view of Humphries et al. (US 4,849,330).

Application Nos. 10/278421 and 10/279788 claim a device (see e.g. claim 1, "nose") comprising at least one porphyrin dye (see e.g. claim 1, "porphyrin"). Application Nos. 10/278421 and 10/279788 do not claim an analyte-specific compound, an analyte, a detectable compound, an enzyme conjugated to the analyte-specific compound, a substrate of the enzyme, a conjugate comprising an enzyme and a non-analyte-specific compound, a capture analyte-specific compound, a tracer comprising an analyte molecule bound to an enzyme, a receptor molecule, and a sample.

However, Humphries et al. describe a device comprising an analyte-specific compound (see col. 8, line 47, "antibodies"), an analyte (see col. 8, lines 49-50, "ligands"), a detectable compound (see col. 9, line 41, "redox material"), an enzyme conjugated to the analyte-specific compound (see col. 10, lines 56-57, "enzyme conjugated to... reciprocal binding pair member"), a substrate of the enzyme (see col. 10, line 51, "substrates"), a conjugate comprising an enzyme and a non-analyte-specific compound (see col. 9, lines 26-29, "label conjugated to... analyte analog"), a capture analyte-specific compound (see col. 11, line 12, "sandwich immunoassay"), a tracer comprising an analyte molecule bound to an enzyme (see col. 9, lines 26-29, "label conjugated to... analyte"), a receptor molecule (see col. 8, line 47, "antibodies"), and a sample (see col. 9, line 28, "sample").

Therefore, it would have been obvious for a person of ordinary skill in the art to modify the tongue, as recited in claim 1 and 26 of Application No. 10/278421, or alternatively, claims 1 and 21 of copending Application No. 10/279788, by placing various immunoassay components on it because Humphries et al.

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discovered a device providing "specific interactions" (see col. 4, line 64) for detecting the presence of "specific components" (see col. 8, lines 33-34) in complex mixtures, such as saliva (see col. 8, lines 40-42).

These are provisional obviousness-type double patenting rejections.

Conclusion

No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Heller & Morrison (US 4,859,583) is cited for an alternative teaching of a "porphyrin dye" (see col. 4, line 26, "iron-porphyrin derivatives").

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

djv



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04/26/05